IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Before The Primary Examiner

In re Application of:
MICHAEL J. SADAR — Group Art Unit: 2877
Serial No. 10/694,152
Filed: October 27, 2003 — Examiner: A. H. Merlino
For: DETECTION OF FILTER BREAKTHROUGH

Attorney Docket No. 100-86

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Commissioner for Patents
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DECLARATION OF MICHAEL J. SADAR

1. I am the named inventor in the above-identified application.

2. I have reviewed the Examiner's statement as set forth in the Office Action mailed August 23, 2006.

3. The Goto et al. patent describes use of relative standard deviation (RSD) of turbidity measurements of a turbidity calibration solution (turbidity calibration standard or calibration standard) to specifically determine if the calibration solution has become stable so that the correct value of the calibration standard itself is representative of its true analytical value. In turbidity measurement, significant error in calibration standards will occur if the calibration standard is not measured under stable conditions.

4. When preparing a turbidity calibration standard for measurement, it must be thoroughly mixed prior to use. During this period of mixing, the calibration solution is typically

inverted to re-suspend the light scattering polymer material (that is contained within the standard and will stratify over time) into a homogeneous mixture. The physical process of this mixing also mixes the air from the head space of the calibration solution's container into the calibration standard. This air causes a significant amount of instability of the calibration standard, which if measured before this air is allowed to vacate the calibration standard will result in an erroneous measurement of the calibration standard. The air is entrained into the calibration standard as bubbles that also scatter light and are a significant interference in turbidity measurement. This air must be dissipated or removed from the calibration standard to allow for an accurate measurement of the standard itself. The same condition of calibration standard instability can result if a calibration standard has to be transferred from its holding container into the instrument that is to be calibrated. During the transfer, air will mix with the calibration standard, which causes an unstable condition. A second condition that can cause a calibration standard to become unstable is when a turbidity standard is allowed to stand for too long a period of time. The suspension of light scattering material will begin to settle. At this point, the RSD of the turbidity standard will begin to increase, indicating that the calibration standard is again unstable and should not be used for taking a calibration measurement from this standard.

5. Goto et al. teaches that if the RSD of the turbidity measurement of a calibration standard is applied, it can be used to monitor the stability of the calibration standard itself. This RSD value will decrease as entrained bubbles have vacated the calibration standard, which is indicative of the calibration standard reaching a stable condition and exhibit its true value. Thus, Goto et al. teaches that a calibration standard value should be taken only under certain conditions, which are reflected by the RSD measurements of that standard. In summary, Goto et al. teaches that a low RSD of a calibration solution indicates that the calibration solution is stable and fit to be measured at a given point in time. Goto does not infer in his patent that the RSD of a turbidity signal can be applied to ascertain the condition of a filtration process in real time. Goto et al. does not cross over from an artificial sample (i.e. calibration standard) to a real-world process. Goto et al. remains with assessing the validity of a calibration solution only.

6. The present invention teaches that under a specific type of turbidity or particle counter signal, additional information from the signal can be extracted and used separately to access the condition of a filtration process, for example, in real time and can do so in the absence of the actual calibrated laser turbidity value that is also generated. Specifically, the RSD as applied in the present invention can increase the sensitivity of

a change in the condition of a filter that would not be observed in the calibrated laser turbidity value. Sensitivity is being defined in this application as having a lower detection level to a breach in a filtration process. The lower the detection level, the better the sensitivity. The detection level would be detected by a change in the RSD of the measurement, but the measurement (calibrated turbidity baseline value) itself would not show a stepped increase in the raw turbidity baseline value. This stepped increase in the turbidity value is what is traditionally used as an indication of a filtration breach.

7. The present application further teaches that the RSD measurement is treated as a separate parameter which is then used in conjunction with the calibrated laser turbidity signal to ascertain the type of filtration breakthrough, in the event that a breakthrough has occurred. The combination of these two parameters can help determine if the particles that are passing through the compromised filter are in the size range that is representative of pathogens and warrant cause for health concerns. The present application discusses four discrete combinations between the calibrated turbidity measurement and RSD for determining the type of particles passing through a compromised filter.

8. The Goto et al. patent does not infer or discuss how the combination of a turbidity signal and RSD can be used to produce qualitative information regarding a filter breach. There is no

combination of the teachings of Banerjee with the teachings of the Goto et al. patent which would lead to the present invention.

9. The present invention requires certain measurement design criteria be met so that the calibrated laser turbidity signals are able to be responsive to low numbers of particles that would begin to influence the incident light beam of the laser turbidimeter, such as during the onset of a filter breakthrough. Specifically, the light source of the instrument must be of a collimated design that provides for an exceptionally defined and narrow light beam as it enters a sample cell. A laser, laser diode or LED light source, either alone or in combination with convergent optics, provides the required projected beam of light. It is only when this condition is satisfied that the RSD parameter can be generated in response to the presence of low numbers of small (micron-sized) particles in the sample stream. This is the condition which allows for the use of the RSD parameter for the detection of a compromised filter.

10. It is only with instrumentation such as those as shown by Banerjee or described in the present application that the RSD value be taken as a discrete measurement that directly correlates to filtration performance. Banerjee fails to describe the use of turbidity measurements for any purpose other than the generation of a calibrated turbidity signal itself. Banerjee

states that only a change in the calibrated turbidity signal signifies a response. Banerjee fails to discriminate the difference between the calibrated turbidity value and the RSD value itself, taken as separate monitoring parameters for the use of detection of a filter breakthrough. Nor does Banerjee combine the information from the two separate parameters (laser turbidity value and RSD or particle count and RSD) to determine qualitative aspects of the measured particles that would be passing through a breached filter.

11. Goto et al. does not discuss the required design criteria to be able to generate a valid separate RSD monitoring parameter as is described in the present application. Goto's use of the RSD can only be found to be beneficial with calibration standards, which when influenced by bubbles or settling of the material will result in significant changes in the RSD. Goto's invention finds itself useful with those turbidimeters that have traditional light sources such as incandescent lamps that project a divergent beam of light. The present application would not find itself useful under such a condition as an incandescent light source.

12. In summary, the present application discovers the unique use of RSD as a separate laser-based turbidity generated or laser-based particle monitoring generated parameter that is used independently of the turbidity or particle counter signal. This separate RSD signal can then be used in combination with

the calibrated turbidity signal to ascertain the nature of the breach of a failed filter system. Goto does not apply the RSD parameter to any condition outside of the boundaries of an instrument calibration or instrument performance and does not transition to measurement quality of said processes that such instrumentation is intended for use.

13. In the Office Action, the examiner states "It is well known in the art that the relative standard deviation is useful in accessing the precision of the measurements which would aid in determining the accuracy and precision of the measuring system (i.e. calibration)." Traditionally, it is common that the RSD be used for determining the precision of the measuring system. It is applied to access the performance of the instrument itself, and nearly all analytical instrumentation carries a statement of measurement precision. However, this precision applies to the instrument itself, which is also how Goto reveals and uses his invention. Contrarily, the present invention uses RSD as a succinct monitoring parameter to assess the integrity of a filtration system. The RSD as used in the present invention monitors against its respective baseline for discrete changes in amplitude. If the amplitude increases over a pre-established limit, then this is indicative of a compromised filter. The RSD when used independently does not require reference back to a calibration value or calibrated turbidity

measurement, or any other parameter. It can be used as an independent measurement of filter integrity, for example.

14. The reason why the RSD can be used independently is due to the conditions of instrument design under which it is applied. When a fine collimated beam of light is impinged by a relatively low number of particles (i.e. 1-10 particles per ml), such as those that would trickle through a filter at the beginning of a breach, the light scatter from the beam will begin to occur. Under this condition, the few particles cause a significant change in the RSD amplitude as they pass independently through the light beam. This number of particles is few but may not be significant to cause a change in the calibrated turbidity measurement value. Thus, the RSD parameter itself signals a precursor condition to a larger filtration breach (only the larger breach will cause the calibrated turbidity measurement to change, which is when a full-blown breach has occurred).

15.Neither the Banerjee nor the Goto teachings provide any description of the application of the RSD parameter that is described in detail in the present application and which uses RSD to increase detection sensitivity to a compromised filter or the precursor to a compromised filtration process. This approach is unique and is not encompassed by any of the prior patents cited by the examiner and used in his rejections of the present claims.

16. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: October 6, 2006

Michael J. Sadar